EXHIBIT S

J & J INTL. - TECHNICAL FILE NO.1 - PROLENE* MESH

J & J INTL. - TECHNICAL FILE NO.1 - VARIATION NO.1

J & J INTL. - TECHNICAL FILE NO.1 - VARIATION NO.2

J & J INTL. - TECHNICAL FILE NO.1 - VARIATION NO.3

J & J INTL. - TECHNICAL FILE NO.1 - VARIATION NO.4

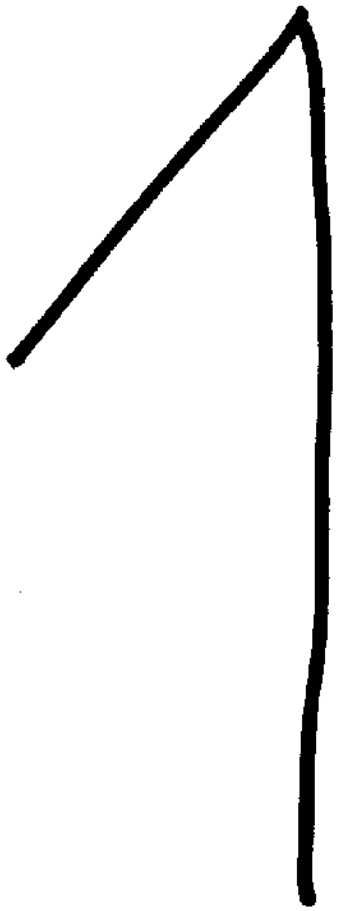
J & J INTL. - TECHNICAL FILE NO.1 - VARIATION NO.5

J & J INTL. - TECHNICAL FILE NO.1 - PROLENE* MESH

TECHNICAL FILE

PROLENE* MESH STERILE POLYPROPYLENE NON ABSORBABLE MESH

INDEX



SECTION 1

PRODUCT CHECKLIST TO SHOW COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

PRODUCT NAME: PROLENE® Mesh Sterile Polypropylene Non Absorbable Mesh

PRODUCT CLASSIFICATION: Class IIb (Rule 8, Annex IX, Medical Device Directive 93/42/EEC)

ESSENTIAL REQUIREMENTS ANNEX I (MDD 93/42/EEC)	METHOD OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS	TECHNICAL FILE REFERENCE	COMMENTS
I. GENERAL REQUIREMENTS			
1. The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	History of safe clinical use. Recent biocompatibility and clinical review. Risk Analysis in accordance with EN 1441. Manufacturer and Sub-Contractors in compliance with BS EN ISO 9001 and EN 46001.	Section 6, p. 108-129 Section 4, p. 47-104 Section 5, p. 105-107 Section 3, p. 37-46	Regulations in the UK from the time of product introduction to date did not require clinical investigation or regulatory approval.

SECTION 1

PRODUCT CHECKLIST TO SHOW COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

PRODUCT NAME: PROLENE* Mesh Sterile Polypropylene Non Absorbable Mesh

PRODUCT CLASSIFICATION: Class IIb (Rule 8, Annex IX, Medical Device Directive 93/42/EEC)

ESSENTIAL REQUIREMENTS ANNEX I (MDD 93/42/EEC)	METHOD OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS	TECHNICAL FILE REFERENCE	COMMENTS
I. GENERAL REQUIREMENTS			
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction) - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated - inform users of the residual risks due to any shortcomings of the protection methods adopted.	BS EN ISO 9001 - Quality Systems Specification for Design/Development, Production, Installation and Servicing. EN 46001 - Specific Requirements for the Application of EN29001 for Medical Devices. EN 724 - Guidance on the Application of Quality Systems for the Non-active Medical Device Industry.	Section 3, p. 37-46	
3. The devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a) as specified by the manufacturer.	History of Safe Use Instructions for Use Leaflet	Section 6, p. 108-129 Appendix II, p.132-135	

SECTION 1

PRODUCT CHECKLIST TO SHOW COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

PRODUCT NAME: PROLENE® Mesh Sterile Polypropylene Non Absorbable Mesh
PRODUCT CLASSIFICATION: Class IIb (Rule 8, Annex IX, Medical Device Directive 93/42/EEC)

ESSENTIAL REQUIREMENTS ANNEX I (MDD 93/42/EEC)	METHOD OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS	TECHNICAL FILE REFERENCE	COMMENTS
I. GENERAL REQUIREMENTS			
4. The characteristics and performance referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	History of Safe Use. Clinical Evaluation in the form of a compilation of relevant scientific literature. Review of clinical data. Risk analysis - BS EN 1441	 Section 6, p. 108-129 Section 4, p. 47-104 Section 5, p. 105-107	 Risk Analysis performed against the requirements of BS EN 1441 Medical Devices - Risk Analysis
5. The devices must be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	History of Safe Use Packaging Stability Studies Instructions for Use Leaflet	 Section 4, p. 47-104 Appendix II, p.132-135	
6. Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.	Risk Analysis - BS EN 1441 Instruction for Use leaflet	Section 5, p. 105-107 Appendix II, p.132-135	Risk Analysis performed against the requirements of BS EN 1441 Medical Devices - Risk Analysis

SECTION 1

PRODUCT CHECKLIST TO SHOW COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

PRODUCT NAME: PROLENE* Mesh Sterile Polypropylene Non Absorbable Mesh

PRODUCT CLASSIFICATION: Class IIb (Rule 8, Annex IX, Medical Device Directive 93/42/EEC)

ESSENTIAL REQUIREMENTS ANNEX I (MDD 93/42/EEC)	METHOD OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS	TECHNICAL FILE REFERENCE	COMMENTS
II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION			
7. Chemical, physical and biological properties			
7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the "General Requirements". Particular attention must be paid to: - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability; - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device;	Toxicological and Biocompatibility testing performed against the requirements of the United States FDA in the mid 1970's. Recent cytotoxicity studies on mesh plus review of previous data.	Section 4, p. 47-104	Testing on mesh minimal because of previous testing of PROLENE suture which is identical in composition.

SECTION 1

PRODUCT CHECKLIST TO SHOW COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

PRODUCT NAME: PROLENE® Mesh Sterile Polypropylene Non Absorbable Mesh

PRODUCT CLASSIFICATION: Class IIb (Rule 8, Annex IX, Medical Device Directive 93/42/EEC)

ESSENTIAL REQUIREMENTS ANNEX I (MDD 93/42/EEC)	METHOD OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS	TECHNICAL FILE REFERENCE	COMMENTS
II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION			
7. Chemical, physical and biological properties			
7.2 The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.	Ethylene oxide residues reduced to levels below those required by ISO 10993-7. Toxicological and Biocompatibility testing performed against the requirements of the United States FDA in the mid 1970's. Recent cytotoxicity studies on mesh. Risk Analysis performed against the requirements of BS EN 1441 - Medical Devices - Risk Analysis.	Section 4, p. 47-104 Section 4, p. 47-104 Section 5, p. 105-107	
7.3 The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.	Risk Analysis performed against the requirements of BS EN 1441 - Medical Devices - Risk Analysis. Instructions for Use Leaflet	Section 5, p. 105-107 Appendix II	

MEDICAL DEVICE DIRECTIVE TECHNICAL FILE

ANNEX I

ESSENTIAL REQUIREMENTS

I. GENERAL REQUIREMENTS

1. **"The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical conditions or the safety of the patients, users and, where applicable, other persons. The risks associated with the devices must be reduced to an acceptable level compatible with a high level of protection of health and safety."**

The design and manufacture of PROLENE * Polypropylene Mesh, manufactured by Ethicon Limited on behalf of Johnson & Johnson International, are currently controlled in compliance with the requirements of Quality System Standard ISO 9001/EN29001, Part 1 - Specification for Design, Development, Production, Installation and Servicing, and also with EN 46001 - Specific Requirements for the Application of EN29001 for Medical Devices. Account has also been taken of the information contained in EN 724 - Guidance on the Application of Quality Systems for the Non Active Medical Device Industry.

The safety of the product has been evaluated by biocompatibility testing and by clinical experience.

The mesh knit has recently been altered to enhance the structural integrity of the cut pieces. The only change was to the knit construction set up. No other process changes were made.

The new knit was validated by Ethicon Inc through all processing stages to ensure equivalence to previous knit mesh. Surgeon preference evaluation was also carried out in hernia repair. Results are contained in 'PROLENE Mesh New Construction Factbook' a copy of which is held by Ethicon Limited. Validation of the packaging and sterilisation processes with the new mesh knit were also carried out at Ethicon Limited. Results are contained in the Factbook - 'Validation of PROLENE Mesh into New Folder', Validation Number 96N-034, held by Ethicon Limited.

2. **"The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art."**

The safety principles used for the original design and construction of the device were those required by the FDA in the United States in the mid 1970's when PROLENE Mesh was first developed. Manufacture by Ethicon Limited was originally to the requirements of the Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products *and is now to EN 29001 and EN4600 as detailed in 1 above.*

3. **"The devices must achieve the performances intended by the manufacturer, ie be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer."**

The claims for performance made by the manufacturer are as follows:-

Each batch complies with the in-house specification for sterile PROLENE Mesh.

PROLENE Mesh elicits a minimal initial inflammatory reaction in tissues which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, incorporating the mesh into adjacent tissue. The mesh is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

Compliance with these standards ensures that PROLENE Mesh performs satisfactorily for the repair of hernia and other fascial deficiencies which require the addition of a reinforcing or bridging material.

Ethicon Limited finished product specification is shown in section 2.12.

The tissue reaction and resistance to absorption claims are supported by studies using implantation of mesh in rabbits which were carried out at the initial development of the material. Studies on PROLENE suture are also relevant. These studies are summarised in section 7.1.2 - Local Effects After Implantation.

4. **"The characteristics and performances referred to in Sections 1 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use."**

   PROLENE Mesh is a single use product. The lifetime of the device is, therefore, the duration of implantation. The studies included in section 7.1.2 show that the mesh is well tolerated by the body.

5. **"The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use are not adversely affected in the storage and transport conditions (temperature, humidity etc.) laid down by the manufacturer."**

   The shelf life of PROLENE Mesh is five and a half years with recommended storage conditions of below 25° C away from moisture and direct heat. Stability studies have been carried out to show that its characteristics and performance are not adversely affected in these conditions. (Ethicon Inc Study No. 594-4; Ethicon Limited Retention Sample Testing Programme).

6. **"Any undesirable side-effects must constitute acceptable risks when weighed against the performances intended."**

   PROLENE Mesh elicits only those adverse reactions which are common to all non-absorbable meshes. Precautions and warnings relating to the use of the device are detailed in the Instructions for Use (see section 13).

   A full risk analysis performed against the requirements of BS EN 1441 - Medical Devices - Risk Analysis has been performed and is included in Section 5.

7.1 TOXICITY AND BIOCOMPATIBILITY

"The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I of the 'General Requirements'. Particular attention must be paid to:

- **the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;**

- **the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device."**

The following toxicity and biocompatibility studies have been carried out on PROLENE polypropylene in either mesh or suture form. A summary of *each study is included.*

The development of polypropylene material took place in the 1960's and testing complied with relevant regulatory requirements at that time. The long history of safe use contraindicates the need to retrospectively test these sutures for their potential effects in the other tests which would be required under EN 30993, Part 1.

A recent literature review on the Biocompatibility of PROLENE Sutures and Implants, plus a Biocompatibility Risk Assessment, are also provided.

STUDY	DESCRIPTION
In-Vitro Cytotoxicity	Agar overlay and Neutral Red Uptake tests using L929 mouse fibroblasts *(Sutures)* (1993).
	Agar overlay only (mesh) with and without extraction (1993).
	Agar Overlay and Mouse Fibroblasts Extraction (Mesh, Ethicon Limited, 1997).
	Mouse Fibroblast Elution (Mesh, Ethicon Inc, 1997).
	Comparative Evaluation of UK and USA Cytotoxicity Studies.
Local Effects after Implantation	*Intramuscular Implantation in rats for* periods up to 18 months. Assessment of tissue reaction and breaking strength (Suture).

Local Effects After Implantation	Intramuscular and subcuticular implantation in rats for periods up to two years. Assessment of tissue reaction (Suture).
	Subcuticular implantation in rats for periods up to 23 months. Assessment of tensile strength (Suture).
	Intramuscular implantation in dogs for periods up to two years. Assessment of tissue reaction (Suture).
	Implantation in ocular tissues in rabbits for periods up to 60 days. Assessment of tissue reaction (Suture).
	Subcutaneous implantation in rabbits for up to 28 days. Assessment of tissue reaction (Mesh).

7.1.1 IN VITRO CYTOTOXICITY STUDIES PERFORMED IN THE UK

In vitro Cytotoxicity Studies - Mouse Fibroblast Extraction Toxicity Assay

Reference: Ethicon Ltd. Report No. 34/97

This study, being applied to a Medical Device, the choice of method is based on assessment of cellular viability of cultured cells by culture medium extracts of the device

1. Test System

Species/Strain	NCTC clone L929 Mouse fibroblasts
Source	Life Technologies, Paisley
Growth	Minimum Essential Medium and 5% foetal calf
Passage	570-600

2. Test Material

A: Non-sterile PROLENE Mesh

- clear, undyed, knitted polypropylene mesh
- six different non-sterile raw material lots

B: Sterile PROLENE Mesh

- sterilised by ethylene oxide
- clear, undyed, knitted polypropylene mesh
- eight finished goods lots

3. Experimental Conditions

- extracts of mesh; 3.0 cm^2 mesh per ml extractant
- mesh cut to 3 x 5 cm pieces
- one 3 x 5 cm piece of mesh per 15ml extractant
- extractant = minimum essential medium with 5% foetal calf serum
- 37°C for 24 hours in glass, no agitation; brief shake at end of incubation
- extract blank controls = glass only for 24 hours
- cells exposed to extracts and dilutions for 24 hours
- 3 doses of each extract
- 8 replicate wells for test and control doses
- extracts removed and cells stained for 3 hours with neutral red vital stain
- after washing, vital stain eluted in acid and optical density measured
- neutral red uptake (% of control) plotted against extract dilution
- cytotoxicity graded according to degree of viability loss

4. Results

- dose-dependent loss of viability (neutral red uptake) measured with all Prolene* Mesh extracts, sterile and non-sterile
- aqueous washing of some mesh samples resulted in a reduction in cytotoxicity of such samples
- under the conditions of these tests, growth medium extracts of polypropylene mesh were moderately or markedly cytotoxic to fibroblasts in culture

In vitro Cytotoxicity Studies - L929 Agar Overlay Cytotoxicity Assay

Reference: Ethicon Ltd. Report No. 34/97

In this study, being applied to a Medical Device, the choice of method is based on assessment of possible direct cytotoxic effects of anchorage-dependent cultured cells by the material itself

1. Test System

Species/Strain	NCTC clone L929 Mouse fibroblasts
Source	Life Technologies, Paisley
Growth	Minimum Essential Medium and 5% foetal calf
Passage	570-600

2. Test Material

A: sterile PROLENE Mesh

- sterilised by ethylene oxide
- clear, undyed, knitted polypropylene mesh
- finished goods lot no. KE4CDKA

3. /

3. Experimental Conditions

- Prolene* Mesh
- mesh cut to squares of 1.0 x 1.0 cm
- squares (one per plate) placed directly on the cell monolayer
- positive control = tin-doped PVC disc
- quadruplicate culture dishes for test and duplicate for control materials
- cells seeded at 3×10^5 per ml, 5ml per plate, and incubated overnight until sub-confluent monolayer obtained
- samples added and cells overlain with 2% agar in culture medium having 5% foetal calf serum
- cells exposed to test and controls for 48 hours at 37°C
- cultures stained with neutral red vital stain for 3 hours
- cell monolayer examined morphologically
- any zones of stain loss measured by image analysis and area recorded
- cytotoxicity graded according to zone araea and cellular morphology

4. Results

- zone formation and slight loss of viability (neutral red uptake) measured with both sterile Prolene* Mesh samples
- under the conditions of these tests, samples of polypropylene mesh were graded as slightly cytotoxic to fibroblasts in culture

7.1.1 IN VITRO CYTOTOXICITY STUDIES PERFORMED IN THE USA

In vitro Cytotoxicity Studies - Mouse Fibroblast ISO Elution Cellular Toxicity Assay

Reference: Ethicon Inc. Report No. PSE 97-0122 and PSE 97-0123

This study, being applied to a Medical Device, the choice of method is based on assessment of possible cytotoxicity to cultured cells by growth medium extracts of the device

1. Test System

Species/Strain	ATCC Clone L929 Mouse Fibroblasts
Source	American Type Culture Collection, Maryland, USA
Growth	From cultured stock. Maintained in Minimum Essential Medium, l-glutamine and 5% serum

2. Test Material

A: non-sterile PROLENE Mesh

- clear, undyed, knitted polypropylene mesh
- two non-sterile raw material lot nos. (1038931515 and 1038931510)

3. Experimental Conditions

- extracts of Prolene* Mesh; 60 cm^2 per 20ml extractant (3.0 cm^2/ml)
- 20 cm^2 piece of mesh in 7ml of extractant
- 37°C for 24-26 hours
- triplicate extracts prepared
- neat extract only tested
- extract vehicle controls at same extraction conditions without mesh
- negative control = low-density polyethylene (USP)
- positive control = tin-doped PVC
- triplicate culture flasks for test and control extracts
- cells exposed to test and controls for 48 hours at 37°C
- cultures examined morphologically and scored according to USP guidelines

4. Results

- cultures dosed with mesh extracts exhibited no evidence of cell lysis or toxicity
- all extract, negative and positive controls behaved as expected
- under the conditions of these tests, growth medium extracts of Prolene* Mesh were non-cytotoxic

7.1.1 COMPARATIVE EVALUATION OF USA & UK CYTOTOXICITY STUDIES

Extract from Report entitled "Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device". Author - Thomas A Barbolt, Research Fellow and L Thomas Divilio, Director Medical Affairs, Ethicon Inc, dated 6.10.97.

Some of the apparent conflicting results from the different testing facilities can be addressed by understanding that slightly differing testing protocols were followed. Although all the testing was described as conforming to ISO 10993-5 guidelines entitled "Biological Evaluation of Medical Devices - Tests for Cytotoxicity: In Vitro Methods", there were some technical differences relating to the extraction procedures, all within the broad guidelines of this standard, which may have influenced the final outcomes.

For example, USP extraction conditions state that both sides of a two-dimensional sample (eg mesh) be included in the calculation of surface area for extraction. Since Ethicon (Scotland) used only one side in the calculation of surface area, they effectively doubled the amount of material extracted compared to the testing conducted at NAmSA. Thus, the test results from NAmSA for the samples of raw material PP mesh ..... indicating no cytotoxicity were considered to most appropriately reflect the potential cytotoxicity of this material.

Conclusion

Polypropylene mesh has been used extensively in humans for many years without clinical evidence of rejection, and has proven to be one of the most inert materials implanted in humans. In addition, healing occurs over exposed mesh providing strong clinical evidence that this material does not impair wound healing and is not cytotoxic in humans. Implantation of a potentially cytotoxic material would be expected to cause impaired wound healing, resulting in non-healing ulcerations and overt evidence of foreign body reaction. This suggests that any potential irritancy of the PP mesh after implantation is self-limiting and minimal when compared to the implantation procedure itself. Thus, this clinical data provides important evidence that the cytotoxicity of the PP mesh observed in vitro does not translate into any clinical significance or adverse patient outcomes.

7.1.1 CYTOTOXICITY IN-VITRO OF DYED PROLENE* MONOFILAMENT POLYPROPYLENE SUTURE

(Ethicon Limited Report No. 39/93, 30.4.93)

Summary

Samples of Metric 1.0 sutures were examined for in-vitro cytotoxicity using the Agar overlay and Extraction/Neutral Red Uptake tests.

Sample Preparation	Sutures were cut to 1 cm lengths for the Agar Overlay Test. Extracts were prepared in serum containing growth medium for 24 hours at 37°C for the Neutral Red Uptake test. Extract strength was 1.0 cm^2/ml.
Cell Line	*NCTC Clone L929 Mouse Fibroblasts* Passage No. 6080-610.
Medium	Minimum Essential Medium (MEM) with Earle's Salts, 5% foetal calf serum, 1nm glutamine, 1% non-essential amino acids, 2.2 g/litre $NaHCO_3$.
Procedure Agar Overlay	Samples were added directly to the cell monolayers in the Agar Overlay system.
Results Agar Overlay	No zone of cytotoxicity was found. Cells were stained and intact.
Procedure Neutral Red Uptake	Extracts and dilutions (50%) were exposed to cells for 24 hours in 96 well microplates. Optical density was read at 540 nm on a microplate reader.
Results Neutral Red Uptake	Little or no reduction in Neutral Red Uptake.

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a Johnson-Johnson company
Department of
Pathology, Toxicology & Surgery

06004

JAN 25 1993

K. Purcell (Cornelia)

cc: S. H. Liu
RDCF

IN VITRO CYTOTOXICITY:
PROLENE POLYPROPYLENE MESH:
LOT #D356 2980 - NORMAL PRODUCTION,
SCOURED AND W/ETHASEW WAX AS A LUBRICANT;
LOT #D42990 - NOT SCOURED AND
W/PARAFFIN OIL AS A LUBRICANT;
LOT #D2949 - SCOURED AND
W/PARAFFIN OIL AS A LUBRICANT

PTS ACCESSION NO.

92-1411

PROJECT NO. 99999

The above-captioned samples, and extracts thereof, were non-cytotoxic when tested in the agar overlay assay. The results of these studies are summarized in the attached copies of the final reports issued by North American Science Associates, Inc. on January 7, 1993.

Lisa Martini 1/25/93
L. Martini, B.S.
Study Coordinator
Associate Scientist, Toxicology

J. F. Dooley 1/25/93
J. F. Dooley, Ph.D.
Principal Scientist, Toxicology

Attachment
G:\92-1411R.LMH

ETHICON INC.
JAN 2 6 1993
RD-CENTRAL FILE

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LOT NO. 92-1411

ATTN: LISA MARTINI

06005

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh Lot #D356 2980; Normal Production, scoured and with Ethasew Wax

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test sample.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Positive Control: P-11102	T	9

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-5-93 Date Terminated: 1-6-93

lms Completed 1-7-93 Tech. LMN/JMT Approved

MG030-110

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06006

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh Lot #D356 2980; Normal Production, scoured and with Ethasew Wax

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test article.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Filter Disc Control: 0.9% SC	N	0
Positive Control: P-11102	T	8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-4-93 Date Terminated: 1-6-93

lms Completed 1-7-93 Tech. KSH/SDR/LMN Approved Jamie M. Price

MG030-130

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LOT NO. 92-1411

ATTN: LISA MARTINI

06007

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh Lot #D42990, not scoured, with Parafin oil as lubricant

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test sample.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Positive Control: P-11102	T	9

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-5-93 Date Terminated: 1-6-93

ims Completed 1-7-93 Tech. LMN/JMT Approved

MG030-110

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LAB NO. 92T-20015-00
P.O. NO. 259155

LOT NO. 92-1411

ETHICON, INCORPORATED
P.O. BOX 151
SOMERVILLE, NJ 08876

ATTN: LISA MARTINI

06008

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh Lot #D42990, not scoured, with Parafin oil as lubricant

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test article.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Filter Disc Control: 0.9% SC	N	0
Positive Control: P-11102	T	8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-4-93 Date Terminated: 1-6-93

lms Completed 1-7-93 Tech. KSH/SDR/LMN Approved

MMA

MG030-130

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LAB NO. 92T-20017-00
P.O. NO. 259155

ETHICON, INCORPORATED
P.O. BOX 151
SOMERVILLE, NJ 08876

LOT NO. 92-1411

06009

ATTN: LISA MARTINI

CYTOTOXICITY - AGAROSE OVERLAY WITH EXTRACTION

Test Article: Prolene polypropylene mesh, Lot #D2949; scoured & with Parafin oil as lubricant

Procedure: The test article was prepared by extracting 60 sq. cm in 20 ml of 0.9% SC in an extraction vessel at 37°C for 24 hour(s). A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. A 0.1 ml portion of the test article extract on a filter paper disc was placed on the solidified overlay surface. Also placed on the agarose surface was: (a) a filter paper disc saturated with 0.1 ml 0.9% SC as a negative control, (b) a 1.0 cm length piece of USP negative control, and (c) a 0.5 cm x 0.5 cm piece of P-11102 as a positive control. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell degeneration or lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test article.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Filter Disc Control: 0.9% SC	N	0
Positive Control: P-11102	T	10

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-4-93 Date Terminated: 1-6-93

lms Completed 1-7-93 Tech. KSH/SDR/LMN Approved

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ETHICON, INCORPORATED
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LOT NO. 92-1411

ATTN: LISA MARTINI

06010

CYTOTOXICITY - AGAROSE OVERLAY

Test Article: Prolene polypropylene mesh, Lot #D2949; scoured & with Parafin oil as lubricant

Test Article Description: Mesh - 1 sq. cm piece

Procedure: A monolayer of L-929 mouse fibroblast cells was grown to confluency and overlaid with Minimum Essential Medium supplemented with serum, antibiotics, neutral red, and agarose. The test article, a 0.5 cm x 0.5 cm piece of P-11102 as a positive control, and a 1.0 cm length piece of USP negative control were placed on the solidified overlay surface. Following incubation for 24 hours, the culture was macroscopically examined for evidence of cell decolorization to determine the zone of cell lysis. Any decolorized zone present was examined microscopically to confirm cell lysis.

Score	Observations
N (Nontoxic)	No change in cell morphology in proximity to test sample.
T (Toxic)	Death and/or degeneration of cells directly beneath the area of test sample and possibly also within a zone extended beyond the test sample. Where a zone of lysis was observed, the distance from the edge of the sample to the edge of the zone was measured and reported in millimeters (mm).

Results:

Test/Control Articles	Score	Zone of Lysis (mm)
Test Article Results	N	0
USP Negative Control	N	0
Positive Control: P-11102	T	8

Conclusion: The above test article was nontoxic for L-929 mouse fibroblast cells under the above described test parameters.

Comments: Not Applicable.
Date Prepared: 1-5-93 Date Terminated: 1-6-93

lms Completed 1-7-93 Tech.LMN/JMT Approved

MG030-110

PLEASE USE YELLOW HIGHLIGHTER PEN TO HIGHLIGHT WORDS ERF Acc. No. 92-1411

1) ADDITIONAL SAMPLE DESCRIPTION
(include only if not in title)

Form:

Mesh	Mono
Staple	Braid
Clip	Dyed
Absorbable	Undyed
Adhesive	Coating_____
Film	Size_____
Coupler	Other_____
Non-absorbable	

2) ADDITIONAL STUDY DESCRIPTION

Study Type:

Tissue reaction	Demonstration
[illegible]orption	Sales School
[illegible]aking strength	Laser
Function	GLP
Developmental	Ex vivo
Product Service Review	In vitro
Product Inquiry Affiliate	Dept. objective
Veterinary inquiry	Training study
Pilot	Competitive test
Cancer	Comparative
Allergen	Patency
Intracutcut Irritat	Stability
Mutagen	Hinge strength
Pyrogen	Tensiometry
Acute tox	Photomicrography
Gross TR	
Other CYTOTOXICITY	

Implant Site:

[illegible]H	Stomach
Eye	Genital tract
Vascular	Lung
IP	Skin
IV	Small intestine
Intradermal	Spleen
Dura	Colon
Urinary bladder	Bone
	Other_____

Implant period-days: List

Test system:

Rat	Cell culture
Mouse	Guinea pig
Rabbit	Pig
Dog	Goat
Human	Other_____

Photography:

Gross photo	Video
Micro photo	SEM photo
TEM photo	Other_____

3) ADDITIONAL HISTOLOGY DESCRIPTION:

Embed:

GMA	Ground section
Frozen section	Other_____

Special Stains:

ORO	Iron
Silver	Calcium
Trichrome	Geimsa
PAS	Gram
PTAH	Immunohistochem
VG	Other_____

Slides, no slides, histopath report

4) SURGICAL DESCRIPTION:

Anastomosis vascular	Keratotomy
Anastomosis-_____	Laparotomy
Colotomy	Lobectomy
Craniotomy	Splenectomy
Cystotomy	Thoracotomy
Gastrotomy	Ligation
Ovariohysterectomy	Other_____

5) MISCELLANEOUS:

Biochem analysis	Other_____
Clinical pathology	Other_____
Radiography	Other_____
Biomechanics test	

7633A/cal

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

Tissue Reaction and Tensile Strength of PROLENE* Polypropylene Suture In-Vivo

(Ethicon Limited Report No. 38/82, 27.9.82)

Summary

Blue dyed PROLENE sutures, gauge sizes metric 1.0, 2.0 and 4.0 were implanted into the lumbar muscle of rats for periods up to 18 months. Three rats were used for histological evaluation and three for breaking strength assessment at each survival time.

Very few rats survived beyond one year due to a pathological problem associated with the strain of rat used.

Tissue Reaction Assessment

Tissue reactions were described qualitatively and assessed quantitatively using a manually operated picture analyser. Tissue reaction areas from 1 to 120 days were between 0.11 and 0.42 mm^2 indicating an extremely low grade reaction which was unchanged at the longest period tested - 18 months.

Tensile Strength Assessment

Straight pull tests using an Instron tester were carried out on the explanted samples. PROLENE was shown to be very resistant to loss of tensile strength at all periods tested.

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

Two Year Study of Tissue Reaction to Colourless and Pigmented Monofilament Polypropylene Sutures in the Dog

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

The biological behaviour of colourless and copper phthalocyanine blue pigmented polypropylene sutures was determined in four dogs in a two year study. Sutures, size 5/0 and 2/0, were implanted in the latissimus dorsi muscle as straight segments, continuous looping stitches, and as interrupted stitches. One dog was killed for histological evaluation of implant site after three months; the remaining three dogs after two years.

On gross examination the severed ends of the implanted segments appeared intact; no untoward reactions were noted.

Microscopically the sutures appeared as translucent, colourless or blue circles or ovals with regular outlines; neither phagocytosis of the implants nor dissolution were observed. Small fragments of polypropylene were seen in the vicinity of a few implants, both colourless and pigmented. These probably shredded off when knots were tied.

The reaction to the suture in most of the sites was slight and consisted of fibrous capsules infiltrated with varying numbers of macrophages. A somewhat larger number of macrophages and lymphocytes was seen in four implants, two colourless and two pigmented sutures. Since part of each of these implants was sutures into both muscle and fascia the increased reaction was probably caused by adhering tissues pulling on the sutures during movements of the animals. The type of reaction to colourless and pigmented sutures was similar as was the reaction after three months and after two years.

No neoplastic changes were observed.

Colourless and pigmented monofilament polypropylene sutures were well tolerated by dog tissue, caused a slight foreign body reaction, were not carcinogenic and were not absorbed within 24 months.

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

Two Year Study of Tissue Reaction to Colourless and Pigmented Monofilament Polypropylene Sutures in the Rat

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

Colourless and phthalocyanine blue pigmented polypropylene sutures, sizes 2/0 and 5/0 were implanted into muscles and subcutis of 100 Sprague-Dawley rats. Rats were killed at intervals over a period of 24 months; implants and tissues were evaluated grossly and microscopically.

The reaction to colourless or pigmented suture in 45 rats maintained on test for 18 months or more was minimal, characteristic of a relatively non-irritating foreign body. The implants were surrounded by thin fibrous capsules whose interphase was infiltrated with few macrophages and fibroblasts. Several capsules hyalinised; giant cells were rarely seen. Reaction to both types of sutures after two years did not differ from that observed at one year. Microscopically, neoplastic changes in proximity of any suture were not observed, and all implants appeared intact grossly and microscopically.

On the basis of the experiment it was concluded that both colourless and pigmented polypropylene sutures were well tolerated by rat tissues, caused minimal foreign body reaction, were not carcinogenic, and were not absorbed during the 24 months test period.

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

Two Year Study of Tissue Reaction to Colourless and Pigmented Polypropylene Sutures in the Ocular Tissues of the Rabbit

(Ethicon Inc Final Report, 14.10.65)

Summary and Conclusions

The reaction to size 5/0 colourless and pigmented sutures in tissue of rabbit eye was investigated in two series of experiments. In one group of 29 albino rabbits straight segments of sutures were placed in the palpebral conjunctiva. Four rabbits from this group were killed at 3, 5, 7, 10, 30 and 60 days after implantation. Histological evaluations were made of 11 sites implanted with colourless sutures and 17 sites implanted with pigmented sutures. In the second experiment sutures were evaluated in the rectus dorsal muscle and palpebral conjunctiva of 20 rabbits. Animals were killed after periods of 3, 7, 30 and 60 days, histological evaluations were made of 32 sites implanted with colourless sutures and 32 sites implanted with pigmented sutures.

Suture implants caused no appreciable damage to host tissues, the most characteristic reaction being a slight chronic imflammation. The implants *retained their original characteristics and appeared to be completely inert.*

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

Tensile Strength Study of Colourless and Pigmented Monofilament Polypropylene Sutures in the Rat

(Ethicon Inc Final Report, 14.10.65)

Tensile Strength

Degree of degradation of tensile strength was determined for 5/0 and 2/0 polypropylene colourless and pigmented sutures, size 5/0 in a group of 35 rats at intervals of 1, 5, 15, 30, 45, 88, 102 and 363 days; size 2/0 in a group of 25 rats at intervals of 3 days, and 1, 3, 6 and 9 months, 19, 22 and 23 months.

Results

Implantation of polypropylene sutures in the subcutis of rats for period as long as 23 months produced no appreciable or consistent loss of tensile strength.

7.1.2 LOCAL EFFECTS AFTER IMPLANTATION

PROLENE Mesh - Biological Evaluation in Rabbits

(Ethicon Inc ERF Accession No. 73-130, 21,8.73)

PROLENE Mesh was implanted subcutaneously in the abdominal wall of 12 albino rabbits for 3 and 28 days to determine its tissue response.

A minimal to slight acute response consisting of transient edema, hemorrage or hyperemia, and inflammatory cell infiltration was elicited by PROLENE Mesh. This reaction was supplanted by moderate fibrous encapsulation of mesh filaments and connective tissue formation in spaces between filaments after one month of implantation.

The reactions to PROLENE Mesh were similar in type and extent to the response elicited by Marlex mesh implanted as a control.

R & D
Ethicon Germany
Dr.Hc
Oct. 1, 1997

Literature Review on Biocompatibility of Prolene Sutures and Implants

The use of polypropylene in various surgical applications is increasing rapidly. The following review which covers scientific articles published from 1962 to 1997, summarizes experimental and clinical findings which have established biological and clinical safety of polypropylene sutures and implants.

Experimental Studies

- Polypropylene Sutures -

Numerous experimental studies were carried out in various tissues of rats, rabbits, dogs, and swine that demonstrated inertnesss of Prolene sutures. Regardless of animal species, tissue reaction to Prolene sutures was commonly associated with an acute inflammatory reaction early after implantation, slightly more than wire and similar to that elicited by other suture materials but considerably less extensive and more transient than by other sutures (Doc. No. 228, 236, 1236, 1423, 2449, 18931, 19570, 21406).

Early and rapid proliferation of connective tissue was observed and after one month, the suture was encapsulated by fibrous tissue, with minimal foreign body reaction over extended periods of implantation and without any sign of neoplastic transformation (Doc. No. 158, 236, 2064, 2992, 4714, 13998).

Histologic examinations of microvascular anastomosis in the rat sutured with polypropylene after 6 months following surgery, showed normal sites with normal vessel lumen size and well-organized re-endothelialization, without intimal hyperplasia at the anastomosis site or thrombosis (Doc. No. 15264).

In rats and guinea pigs, Gittes and Foreman (Doc. No. 11180) found that Prolene skin sutures with totally buried knots became fully incorporated in the deep tissue without any sign of inflammation at seven weeks.

These experiments have demonstrated the excellent biological tolerance of polypropylene suture material even in tissues sensitive to foreign bodies.

In view of its confirmed inertness, Prolene was often used as reference material in studies comparing different sutures (Doc. No 3324, 4197, 5371, 7165, 6378, 9303, 11817, 13125, 13362, 16728).

- Prolene Mesh -

Comparable results were obtained by Gilbert (Doc. No. 15072) who confirmed in laboratory animals (rabbit model) the assertion that the inflammatory response to Prolene mesh „is no different than it is to polypropylene suture material".

Layman et al. (Doc. No. 16208) tested Prolene mesh in a swine model using a standardized laparoscopic herniorrhaphy technique that consisted of stapling the prosthetic mesh over the hernia defect without peritoneal dissection.

After three months, light microscopy revealed good collagen ingrowth in all Prolene meshes. The inner surface was covered by a thin layer of connective tissue and mesothelial lining. Cellular activity around the mesh showed the presence of chronic inflammatory cells to a mild degree.

Beets et al. (Doc. No. 20152) found giant cells only occasionally at the mesh-tissue interface at 3 to 12 weeks after implanting Prolene mesh preperitoneally in pigs.

Klosterhalfen et al. (Doc. No. 20806) characterized the long term behaviour of Prolene mesh. They implanted it in the abdominal wall of the rat after creating a defect that involved the fascia, the peritoneum and the M. rectus abdominis. Microscopic examinations carried out between the 3rd and 90th day after implantation revealed an intense inflammatory reaction presented by massive aggregation of neutrophil granulocytes on the 3rd day. That reaction decreased significantly during the following period of observation, proceeding to a chronic inflammatory reaction with macrophages.

From the 21st day onwards, edema was hardly distinguishable. It disappeared completely by the 90th day after implantation. On the 90th day, the mesh material was surrounded by a granulomatous capsule with features of secondary acute or chronic inflammation.

Maekisalo et al. (Doc. No. 13034) examined different Prolene mesh sites (subcutaneous, intraperitoneal, femoral bone tunnel) in rats. The amount of scar tissue formed was most prominent round the intraperitoneal implants with distinct maturation of the granulation tissue into fibroblastic connective tissue being completed by the 12th week. Infections or adverse reactions were not observed.

In an abdominal wall defect model in the rat, Simmermacher et al. (Doc. No. 13737) saw the polypropylene mesh fully incorporated in fibrocollagenous tissue after 8 weeks.

Clarke et al. (Doc. No. 19472) who used Prolene mesh for abdominal wall repair in the dog model, report a similar finding. In their 1-, 2-, and 4-month evaluations, they found the Prolene mesh incorporated into connective tissue and surrounded by a dense connective tissue capsule, without any evidence of suppuration, infection, or any type of rejection reaction.

Placed in direct contact with the gastrointestinal tract, Prolene mesh caused adhesions (Doc. No. 13737, 16946, 19472, 19523).

From these experimental findings in different areas of the body including the subcutaneous space, the abdominal wall, intraperitoneal tissue and bone, it can be concluded that vital tissue develops around the Prolene mesh. Its biological behaviour is characterized by a typical acute foreign body reaction which significantly decreases with time, followed by distinct maturation of the surrounding connective tissue.

Summarizing, findings from experimental studies establish an excellent biotolerance of Prolene mesh.

Clinical Experiences

- Prolene Sutures -

For more than 30 years, Prolene suture has been commonly used in surgery to approximate a wide variety of tissues such as skin, subcutaneous tissues, skeletal muscle, tendon, ligament, periosteum, gastrointestinal tract, blood vessels, peripheral nerves, demonstrating its efficacy and safety even in contaminated wounds (Doc. No. 158, 228, 236, 1423, 2449).

Prolene has been extremely resistant to the effects of residence in living human tissue over long periods of time. Histologic evaluation of Prolene suture sites retrieved after several years of residence revealed a minimal tissue response. The sutures were found encapsulated in fibrous tissue with some fibrocytes present. (Doc. No. 5475)

- Prolene Mesh -

Prolene mesh has been widely used in

- inguinal hernia repair,
  conventional surgical technique (Doc. No. 11379, 14123, 14894, 15072, 16011, 20715, 20718, 21360, 21435),
  or laparoscopic technique (Doc. No. 16290, 16708, 19666, 20042, 20154, 21244, 21360, 21435)

- incisional hernia repair (Doc. No. 9831, 19761, 21363)

- repair of abdominal wall defects (Doc. No 6174, 8342, 8879, 13822, 20702)

- repair of chest wall defects (Doc. No. 9385, 12127, 16211, 21071)

- for colposuspension in treatment of urinary incontinence
  (Doc. No. 17194, 17777, 19594, 20010, 20062, 20097)

- rectopexy (Doc. No. 14790, 15849, 21137)

- colposacropexy (Doc No. 12873, 16505, 20017)

and occasionally in diaphragm repair (Doc. No. 6698, 21401) and gastroplasty procedures (Doc. No. 14876, 21187).

Stoppa and Soler (Doc. No. 2983) state that Prolene mesh among other meshes „correctly fit the criteria for a satisfactory biological tolerance". They remark that Prolene mesh offers permeability to the connective tissue cells enabling the mesh framework to soon be inhabited by fibrocytes and thus be incorporated into the tissue. According to them, polypropylene meshes demonstrate a low incidence of seroma formation (4-6%) and a good tolerability in the case of sepsis (0.2-2%).

Their observation is confirmed by other authors who did not remove the mesh when early infection occurred. Through local treatment by antibiotics and drainage, the infection subsided with the mesh left in place (Doc. No. 11379, 19030, 20718, 21071).

Capozzi et al. (Doc. No. 11379) who removed a Prolene mesh from a patient four months after inguinal hernioplasty for pain, found the mesh to be totally incorporated with an impressive strength of the fibrotic reaction seen in the gross specimen and confirmed by histologic examination. They state that the strength of the mesh added to the fibroblastic proliferation that occurred within the mesh produced a very strong inguinal floor.

Fuchsjaeger et al (Doc. No. 18444) examined a Prolene plug site that was explanted 6 months after inguinal hernia repair, by light microscopy. The Prolene mesh was fully incorporated with mild fibrotic reaction while inflammatory or giant cells were rarely present.

There are scant case reports on seroma or late bacterial infections that resolved only after the meshes were eventually explanted (Doc. No. 16708, 19761, 21299).

Summarizing, experimental and clinical studies demonstrate the relative inertness and biocompatibility of Prolene sutures and implants. Throughout the studies reviewed, tissue reaction to these materials is described as acute inflammatory gradually subsiding to a mild degree, with minimal foreign body reaction over extended periods of implantation. Within few weeks, Prolene mesh is fully incorporated into connective tissue. It demonstrates a low incidence of seroma formation and a good tolerability in the case of infection. There is no clinical evidence that Prolene mesh would impair wound healing or elicit any unfavourable effects on cells and tissues. These observations have been made in a variety of tissues.

Dr. med. B. Hellhammer
Mgr. Scientific Information and Documentation

Record No.	158
Authors	Miller, J.M. Kimmel, L.E.
Original Title	**Clinical Evaluation of Monofilament Polypropylene Suture**
Bibliogr. Data	American Surgeon 33 (8) 666-670 (1967)
Record No.	228
Authors	Usher, F.C. Allen, J.E. Crosthwait, R.W. Cogan, J.E.
Original Title	**Polypropylene Monofilament - A New, Biologically Inert Suture for Closing Contaminated Wounds -**
Bibliogr. Data	JAMA 179 (10) 780-782 (1962)
Record No.	236
Authors	Ulin, A.W.
Original Title	**PROLENE Polypropylene suture Nonabsorbable Surgical Suture, U.S.P.**
Bibliogr. Data	Unpublished personal report, Ethicon, Somerville, USA, 1970
Record No.	1236
Authors	Salthouse, T.N. Matlaga, B.F. O'Leary, R.K.
Original Title	**Microspectrophotometry of Macrophage Lysosomal Enzyme Activity: A Measure of Polymer Implant Tissue Toxicity**
Bibliogr. Data	Toxicology and Applied Pharmacology 25 (2) 201-211 (1973)
Record No.	1423
Authors	Miller, J. M.
Original Title	**Evaluation of a New Surgical Suture (Prolene)**
Bibliogr. Data	The American Surgeon 39 (1) 31-39 (1973)
Record No.	2064
Authors	Salthouse, T. N. Matlaga, B.F.
Original Title	**Significance of Cellular Enzyme Activity at Nonabsorbable Suture Implant Sites: Silk, Polyester and Polypropylene**
Bibliogr. Data	J. Surg. Res. 19 (2) 127-132 (1975) SIR 75-388
Record No.	2449
Authors	Orringer, M.B. Appleman, H.D. Argenta, L. Bove, E. Cimmino, V.
Original Title	**Polypropylene Suture in Esophageal and Gastrointestinal Operations**
Bibliogr. Data	Surgery, Gyn. & Obst. 144 (1) 67-70 (1977)
Record No.	2983
Authors	Stoppa, R. Soler, M.
Original Title	**Chemistry, Geometry and Physics of Mesh Materials**
Bibliogr. Data	Auszug aus En-33: Inguinal Hernia Repair, Seiten 166-171 (1995) Karger Verlag (eds.: Schumpelick, V. / Wantz, G.E)
Record No.	2992
Authors	Salthouse, T.N. Matlaga, B.F. Wykoff, W.H.
Original Title	**Comparative Tissue Response to Six Suture Materials in Rabbit Cornea, Sclera and Ocular Muscle**
Bibliogr. Data	Am. J. Ophthalmol. 84 (2) 224-233 (1977) SIR 77-452
Record No.	3324

Authors — Bertin, J. Lasry, G. Lange, F. Melliere, D.
Original Title — **Comparison of Tissue Reaction to four Synthetic Sutures Used for Anastomosis of Small Caliber Arteries**

Bibliogr. Data — Ann. Chir. 31 (8) 707-10 (1977) SIR 78-110

Record No. — 4197
Authors — Thuemler, P. Reinhard, V. Elbing, H.
Original Title — **Faszikulaere Nervennaehte mit synthetischem resorbierbarem Nahtmaterial (Polyglactin 910) (Erste tierexperimentelle Erfahrungen)**
Fascicular Nerve Anastomoses with Synthetic Absorbable Sutures (Polyglactine 910) - First experimental experiences
Bibliogr. Data — Orthopaedische Praxis 15 (2) 154-158 (1979)

Record No. — 4714
Authors — Postlethwait, R.W.
Original Title — **Five Year Study of Tissue Reaction to Synthetic Sutures**

Bibliogr. Data — Ann. Surg. 190 (1) 54-57 (1979)

Record No. — 5371
Authors — Sezeur, A. et al.
Original Title — **Comparative Study of Slowly Resorbing Sutures in the Rat Trachea**

Bibliogr. Data — J. Chir. 117 (4) 265-271 (1980) SIR 80-509

Record No. — 5475
Authors — Salthouse, T.N.
Original Title — **Biologic Response to Sutures**

Bibliogr. Data — Otolaryngol Head Neck Surg. 88, 658-664 (1980)

Record No. — 6174
Authors — Stone, H.H. Fabian, T.C. Turkleson, M.L. Jurkiewicz, M.J.
Original Title — **Management of Acute Full-thickness Losses of the Abdominal Wall**

Bibliogr. Data — Ann. Surg. 193 (5) 612-618 (1981) SIR 82-257

Record No. — 6378
Authors — Tscheliessnigg, K.H. Stadler, H. Hoefler, H. Hellbom, B. Kraft-Kinz, J.
Original Title — **Resorbierbares Nahtmaterial im Rahmen der Herz- und Gefaesschirurgie?**

Bibliogr. Data — Chirurg 54 (11) 738-741 (1983)

Record No. — 6698
Authors — Lacey, S.R. Goldthorn, J.F. Kosloske, A.M.
Original Title — **Repair of Agenesis of the Hemidiaphragm by Prosthetic Materials**

Bibliogr. Data — Surg. Gynecol. Obstet. 156 (3) 310-312 (1983)

Record No. — 7165
Authors — *Guedon, C. Brousse, N. Gehanno, P.*
Original Title — **Biologic comparison of polypropylene, polyglactine 910 and polydioxanone for tracheal, esophageal and muscular sutures in the rabbit**

Bibliogr. Data — *Annales de Chirurgie 37 (6) 443-448 (1983)*

Record No. 8342
Authors McDonald, S. Gagic, N.
Original Title **Intraperitoneal Prolene Mesh in Hernia Repair: A Comparison of Two Techniques**

Bibliogr. Data The Canadian J. of Surgery 27 (2) 157-59 (1984) SIR 84-565

Record No. 8879
Authors Carreirao, S. Correa, W.E. Dias, L.C. Pitanguy, I.
Original Title **Treatment of Abdominal Wall Eventrations Associated with Abdominoplasty Techniques**

Bibliogr. Data Aesth. Plast. Surg. 8, 173-179 (1984)

Record No. 9303
Authors Scheidel, P.H. Wallwiener, D.R. Hollaender, D. Hepp, H.K.
Original Title **Absorbable or Nonabsorbable Suture Material for Microsurgical Tubal Anastomosis - Randomized Experimental Study on Rabbits -**

Bibliogr. Data Gynecol. obstet. Invest. 21, 96-102 (1986)

Record No. 9385
Authors Sando, W. Jurkiewicz, M.J.
Original Title **An Approach to Repair of Radiation Necrosis of Chest Wall and Mammary Gland**

Bibliogr. Data World J. Surg. 10 (2) 206-219 (1986)

Record No. 9831
Authors Kjeldsen, H. Gregersen, B.N.
Original Title **Giant Incisional Hernias Closed with Polypropylene Mesh**

Bibliogr. Data Scand. J. Plast. Reconstr. Surg. 20 (1) 119-121 (1986)

Record No. 11180
Authors Gittes, R.F. Foreman, R.
Original Title **Transcutaneous Incorporation of Nonabsorbable Monofilament Sutures**

Bibliogr. Data Surg. Gynecol. Obstet. 166 (6) 545-548 (1988)

Record No. 11379
Authors Capozzi, J.A. Berkenfield, J.A. Cherry, J.K.
Original Title **Repair of Inguinal Hernia in the Adult with Prolene Mesh**

Bibliogr. Data Surg. Gynecol. Obstet. 167 (2) 124-128 (1988)

Record No. 11817
Authors Beauchamp, P.J. Guzick, D.S. Held, B. Schmidt, W.A.
Original Title **Histologic Response to Microsuture Materials**

Bibliogr. Data Journal of Reproductive Medicine 33 (7) 615-623 (1988)

Record No. 12127
Authors Morgan, R.F. Edgerton, M.T. Wanebo, H.J. Daniel, T.M. et al.
Original Title **Reconstruction of Full Thickness Chest Wall Defects**

Bibliogr. Data Ann. Surg. 207 (6) 707-716 (1988) SIR 89-088

Record No. 12873
Authors Baker, K.R. Beresford, J.M. Campbell, C.
Original Title **Colposacropexy With Prolene Mesh**

Bibliogr. Data	Surg. Gynecol. Obstet. 171 (1) 51-54 (1990)
Record No.	13034
Authors	Maekisalo, S.E. Paavolainen, P. Groenblad, M. Holmstroem, T.
Original Title	**Tissue reactions around two alloplastic ligament substitute materials: experimental study on rats with carbon fibres and polypropylene**
Bibliogr. Data	Biomaterials 10 (2) 105-108 (1989)
Record No.	13125
Authors	di Marzo, L. Hunter, W.J. Schultz, R.D. Feldhaus, R.J.
Original Title	**In Vivo Study of Expanded Polytetrafluoroethylene Vascular Suture**
Bibliogr. Data	Vasc. Surg. 23 (2) 77-82 (1989) SIR 89-202
Record No.	13362
Authors	Metz, S.A. Chegini, N. Masterson, B.J.
Original Title	**In Vivo Tissue Reactivity and Degradation of Suture Materials: A Comparison of Maxon and PDS**
Bibliogr. Data	J. Gynecol. Surg. 5 (1) 37-46 (1989)
Record No.	13737
Authors	Simmermacher, R.K.J. Bleichrodt, R.P. Schakenraad, J.M.
Original Title	**A New Principle in the Repair of Abdominal Wall Defects: the Double-Layer Patch**
Bibliogr. Data	Eur. Surg. Res. 22 (Suppl. 1) 23 (1990) SIR 90-464
Record No.	13822
Authors	Cederna, J.P. Davies, B.W.
Original Title	**Total Abdominal Wall Reconstruction**
Bibliogr. Data	Ann. Plast. Surg. 25 (1) 65-70 (1990) SIR 27030
Record No.	13998
Authors	Banic, A. Francis, I. Nilsson, U.
Original Title	**A Comparative Study of the Use of 9-0 PDS and 9-0 Prolene in Microvascular Anastomosis**
Bibliogr. Data	J. Reconstr. Microsurg. 6 (3) 293-297 (1990) SIR 90-553
Record No.	14123
Authors	Vara-Thorbeck, R. Ruiz-Morales, M. Moreno-Delgado, A.
Original Title	**Leistenbruchoperationen nach Thovara**
Bibliogr. Data	Zbl. Chirurgie 116 (12) 745-749 (1991)
Record No.	14790
Authors	Sainio, A.P. Halme, L.E. Husa, A.I.
Original Title	**Anal Encirclement with Polypropylene Mesh for Rectal Prolapse and Incontinence**
Bibliogr. Data	Dis. Colon Rectum 34 (10) 905-908 (1991)
Record No.	14876
Authors	Mason, E.E.
Original Title	**Vertical Banded Gastroplasty for Obesity**
Bibliogr. Data	Arch. Surg. 117, 701-706 (1982)

Record No.	14894
Authors	Kemen, M. Fink, M. Bauer, K.H. Zumtobel, V.
Original Title	**Reparation der Problemrezidivleistenhernie mit Prolenenetz - 4-Jahres-Ergebnisse**
Bibliogr. Data	Akt. Chir. 27 (2) 95 (1992)
Record No.	15072
Authors	Gilbert, A. I.
Original Title	**Sutureless Repair of Inguinal Hernia**
Bibliogr. Data	American J. of Surgery 163 (3) 331-335 (1992)
Record No.	15264
Authors	Chen, L. E. Seaber, A. V. Urbaniak, J. R.
Original Title	**Microvascular anastomoses in growing vessels - a long-term evaluation of nonabsorbable suture materials**
Bibliogr. Data	J. Reconstructive Microsurgery 9 (3) 183-189 (1993)
Record No.	15849
Authors	Koeckerling, F. Gastinger, I. Gall, C.W. Schneider, B. Krause, W. Gall, P.P.
Original Title	**Laparoskopische Rektopexie**
Bibliogr. Data	Minimal Invasive Chirurgie 1 (2) 68-72 (1992)
Record No.	16011
Authors	Stierli, P. Pfister, J. Aeberhard, P.
Original Title	**Die Behandlung der Rezidivinguinalhernie durch die Einlage einer praeperitonealen Prothese Resultate einer prospektiven Studie**
Bibliogr. Data	Chirurg 64 (4) 334-337 (1993)
Record No.	16208
Authors	Layman, T. S. Burns, R. P. Chandler, K. E. Russell, W. L. Cook, R. G.
Original Title	**Laparoscopic Inguinal Herniorrhaphy in a Swine Model**
Bibliogr. Data	Am. Surg. 59 (1) 13-19 (1993)
Record No.	16211
Authors	Mansour, K. A. Anderson, T. M. Hester, T. R.
Original Title	**Sternal Resection and Reconstruction**
Bibliogr. Data	Ann. Thorac. Surg. 55 (4) 838-843 (1993)
Record No.	16290
Authors	Arregui, M. E. Navarrete, J. Davis, C. J. Castro, D. Nagan, R. F.
Original Title	**Laparoscopic inguinal herniorrhaphy Techniques and Controversies**
Bibliogr. Data	Surg. Clin. North Am. 73 (3) 513-527 (1993)
Record No.	16505
Authors	Volz, J. Strittmatter, H. Volz, E. Koester, S. Wischnik, A. Melchert, F.
Original Title	**Die pelviskopische Sakropexie zur Therapie des Vaginalprolapses** Pelviscopic sacropexy for treatment of vaginal prolapse
Bibliogr. Data	Geburtsh. u. Frauenheilk. 53 (10) 705-708 (1993)

Record No. 16708
Authors Sandbichler, P. Gatir, K. Baumgartner, C. Furtschegger, A. Egender, G. Steiner, E.
Original Title **Laparoskopische Leistenhernienoperation durch transperitoneale Implantation eines Kunststoffnetzes. Technik und Fruehergebnisse**
Laparoscopic inguinal hernia repair by preperitoneal implantation of a prosthetic mesh. Technique and early results
Bibliogr. Data Chirurg 65 (1) 64-67 (1994)

Record No. 16728
Authors Gersak, B.
Original Title **Presence of calcium in the vessel walls after end-to-end arterial anastomoses with polydioxanone and polypropylene sutures in growing dogs**

Bibliogr. Data J. Thorac. Cardiovasc. Surg. 106 (4) 587-591 (1993)

Record No. 16946
Authors Schlechter, B. Marks, J. Shillingstad, R.B. Ponsky, J.L.
Original Title **Intraabdominal mesh prosthesis in a canine model**

Bibliogr. Data Surg. Endosc. 8 (2) 127-129 (1994)

Record No. 17194
Authors Ou, C.-S.
Original Title **Modified Laparoscopic Retropubic Colposuspension with Hernia Staples and Mesh**

Bibliogr. Data Surg. Endosc. 8 (5) 550 (1994)

Record No. 17777
Authors Ou, C- S. Presthus, J. Beadle, E.
Original Title **Laparoscopic Bladder Neck Suspension Using Hernia Mesh and Surgical Staples**

Bibliogr. Data J. Laparoendosc. Surg. 3 (6) 563-566 (1993)

Record No. 18444
Authors Fuchsjaeger, N. Feichter, A. Kux, M.
Original Title **Die Lichtenstein-Plug-Methode zur Reparation von Rezidivleistenhernien. Indikation, Technik und Ergebnisse**
Indication and results of the Lichtenstein plug repair for recurrent inguinal hernias
Bibliogr. Data Chirurg 66 (4) 409-412 (1995)

Record No. 18931
Authors Bakkum, E.A. Dalmeijer, R.A.J. Verdel, M.J.C. Hermans, J. van Blitterswijk, C.A. Trimbos, J.B.
Original Title **Quantitative analysis of the inflammatory reaction surrounding sutures commonly used in operative procedures and the relation to postsurgical adhesion formation**

Bibliogr. Data Biomaterials 16 (17) 1283-1289 (1995)

Record No. 19030
Authors Laporte, E. Semeraro, C. Viceno, C.
Original Title **Inguinal hernioplasty by laparoscopy: our experience of 4 years**

Bibliogr. Data Br. J. Surg. 82 (Supplement 1) 65 (1995)

Record No.	19472
Authors	Clarke, K.M. Lantz, G.C. Salisbury, S.K. Badylak, S.F. Hiles, M.C. Voytik, S.L.
Original Title	**Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs**
Bibliogr. Data	J. of Surgical Research 60 (1) 107-114 (1996)
Record No.	19523
Authors	Dudai, M. Wind, G. Herbert, M. Averbuch, F.
Original Title	**Experimental Laparoscopic Use of a Composite Mesh to Reduce Adhesion Formation**
Bibliogr. Data	Surg. Endosc. 10 (2) 230 (1996)
Record No.	19570
Authors	DeNardo, C. A. Brown, N. O. Trenka-Benthin, S. Marretta, S. M.
Original Title	**Comparison of Seven Different Suture Materials in the Feline Oral Cavity**
Bibliogr. Data	J. Am. Animal Hosp. Assoc. 32 (2) 164-172 (1996)
Record No.	19594
Authors	Evans, R. M. Bernnard, P. H. Zhang, Q. K. Wong, H. Y. Reddy, P. K.
Original Title	**Laparoscopic cutureless Burch procedure**
Bibliogr. Data	J. Endourol. 9 (Suppl.,1) 70 (1995)
Record No.	19666
Authors	Bittner, R. Leibl, B. Kraft, K. Daeubler, P. Schwarz, J.
Original Title	**Die laparoskopische Herniaplastik (TAPP) - Komplikationen und Rezidive bei 900 Operationen** Laparoscopic herniorrhaphy (TAPP) - complications and recurrences following 900 operations
Bibliogr. Data	Zentralbl. Chir. 121 (4) 313-319 (1996)
Record No.	19761
Authors	Tomudom, T. Siadati, M. Sarr, M.G.
Original Title	**Repair of complex giant or recurrent ventral hernias by using tension free intraparietal prosthetic mesh (Stoppa technique): Lessons learned from our initial experience (fifty patients)**
Bibliogr. Data	Surgery 120, 738-744 (1996)
Record No.	20010
Authors	Konrad, G. Weidenfeld, W.-H. Pruetzmann-Steinmetz, A. Hoepffner, H.-J. Landgrebe, S.
Original Title	**Die Schmetterlingurethrozystovaginopexie zur Loesung schwieriger Descensusprobleme**
Bibliogr. Data	Urologe B 36 (6) 466-472 (1996)
Record No.	20042
Authors	Horeyseck, G. Roland, F. Rolfes, N.
Original Title	**Die "spannungsfreie" Reparation der Leistenhernie: laparoskopisch (TAPP) versus offen (Lichtenstein)** Tension-free inguinal repair: laparoscopic (TAPP) vs open (Lichtenstein)
Bibliogr. Data	Chirurg 67 (10) 1030-1040 (1996)
Record No.	20062

Authors: Emmott, R.C. Jurow, A. Kardos, L. Dyer, L.
Original Title: **Laparoscopic Bladder Neck Suspension**

Bibliogr. Data: Min. Inv. Ther. & Allied Techn. 5 (Supplement 1) 32, (1996)

Record No. 20097
Authors: Ulmsten, U. Henriksson, L. Johnson, P. Varhos, G.
Original Title: **An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence**

Bibliogr. Data: Int. Urogynecol. J. 7, 81-86 (1996)

Record No. 20152
Authors: Beets, G. L. Go, P. M. N. Mameren van, H.
Original Title: **Foreign Body Reactions to Monofilament and Braided Polypropylene Mesh Used as Preperitoneal Implants in Pigs**

Bibliogr. Data: Eur. J. Surg. 162 (10) 823-825 (1996)

Record No. 20154
Authors: Friis, E. Lindahl, F.
Original Title: **The Tension-free Hernioplasty in a Randomized Trial**

Bibliogr. Data: Am. J. Surg. 172 (4) 315-319 (1996)

Record No. 20702
Authors: Kind, G.M. Rademaker, A.W. Mustoe, T.A.
Original Title: **Abdominal-Wall Recovery Following TRAM Flap: A Functional Outcome Study**

Bibliogr. Data: Plast. Reconstr. Surg. 99 (2) 417-423 (1997)

Record No. 20715
Authors: Schmitz, R. Treckmann, J. Shah, S. Schneider, K.
Original Title: **Die "Tension-free-Technik" bei offener Leistenhernienreparation. Eine prospektive, randomisierte Studie zur postoperativen Schmerzperception (Tension-free-Rekonstruktion vs. Shouldice-Technik)**
The tension-free technique in open inguinal hernia repair. A prospective randomized study concerning postoperative pain
Bibliogr. Data: Chirurg 68 (3) 259-263 (1997)

Record No. 20718
Authors: Pans, A. Desaive, C. Jacquet, N.
Original Title: **Use of a preperitoneal prosthesis for strangulated groin hernia**

Bibliogr. Data: Br. J. Surg. 84 (3) 310-312 (1997)

Record No. 20006
Authors: Klosterhalfen, B. Klinge, U. Henze, U. Bhardwaj, R. Conze, J. Schumpelick, V.
Original Title: **Morphologische Korrelation der funktionellen Bauchwandmechanik nach Mesh-Implantation**
Morphological correlation of the functional mechanics of the abdominal wall after mesh implantation
Bibliogr. Data: Langenbecks Arch. Chir. 382 (2) 87-94 (1997)

Record No. 21071
Authors: Steinau, H.U. Hebebrand, D. Vogt, P. Peter, F. Tosson, R.
Original Title: **Plastische Rekonstruktion von Thoraxwanddefekten**
Plastic surgery reconstruction of thoracic-wall defects
Bibliogr. Data: Chirurg 68 (5) 461-468 (1997)

Record No.	21137
Authors	Galili, Y. Rabau, M.
Original Title	**Comparison of Polyglycolic Acid and Polypropylene Mesh for Rectopexy in the Treatment of Rectal Prolaps**
Bibliogr. Data	Eur. J. Surg. 163, 445-448 (1997)
Record No.	21187
Authors	Amaral, J. F. Meltzer, R. C.
Original Title	**Laparoscopic surgery for morbid obesity**
Bibliogr. Data	Society for Minimally Therapy, SMIT, Berlin, Oktober 1994
Record No.	21244
Authors	Kald, A. Anderberg, B. Carlsson, P. Park, P. O. Smedh, K.
Original Title	**Surgical Outcome and Cost-Minimisation-Analyses of Laparoscopic and Open Hernia Repair: A Randomised Prospective Trial with One Year Follow Up**
Bibliogr. Data	Eur. J. Surg. 163 (7) 505-510 (1997)
Record No.	21299
Authors	Aytan, L. Avci, C. Bulut, T. Fourtanier, G.
Original Title	**Mesh Infections After Laparoscopic Inguinal Hernia Repair**
Bibliogr. Data	Surgical Laparoscopy & Endoscopy 7 (3) 192-195 (1997)
Record No.	21360
Authors	Corcione, F. Cristinzio, G. Maresca, M. Cascone, V. Titolo, G. Califano, G.
Original Title	**Primary inguinal hernia: the held-in-mesh repair**
Bibliogr. Data	Hernia 1 (1) 37-40 (1997)
Record No.	21363
Authors	Chevrel, J.P. Rath, A.M.
Original Title	**The use of fibrin glues in the surgical treatment of incisional hernias**
Bibliogr. Data	Hernia 1 (1) 9-14 (1997)
Record No.	21401
Authors	Orita, M. Okino, M. Yamashita, K. Morita, N. Esato, K.
Original Title	**Laparoscopic repair of a diaphragmatic hernia through the foramen of Morgagni**
Bibliogr. Data	Surg. Endosc. 11 (6) 668-670 (1997)
Record No.	21406
Authors	Debus, E.S. Sailer, M.A. Geiger, D. Thiede, A.
Original Title	**Comparison of five intracutaneous sutures: an experimental and clinical study**
Bibliogr. Data	Br. J. Surg. 84 (Suppl. 2) 68 (1997)
Record No.	21435
Authors	Zieren, J. Zieren, H.U. Jacobi, C.A. Mueller, J.M.
Original Title	**Die Plug- und Patch-Reparation zur Versorgung der Leistenhernie des Erwachsenen** The Plug and Patch technique for inguinal hernia repair in adults
Bibliogr. Data	Zentralbl. Chir. 122 (7) 545-550 (1997)

Record No. 21464
Authors Miller, K. Junger, W.
Original Title **Ileocutaneous fistula formation following laparoscopic polypropylene mesh hernia repair**

Bibliogr. Data Surg. Endosc. 11 (7) 772-773 (1997)

ETHICON, INC.
a Johnson & Johnson company

P.O. BOX 151
SOMERVILLE, NEW JERSEY 08876-0151

October 1, 1997

To: G. Robertson

Re: Biocompatibility Risk Assessment for PROLENE* Polypropylene Mesh

PROLENE mesh has been used extensively in humans for many years without adverse clinical reactions, and has proven to be one of the most inert materials available for implantation. Both PROLENE mesh and PROLENE* polypropylene suture are manufactured using the same polypropylene resin. The biocompatibility of this material has been demonstrated using a wide variety of preclinical testing methods. Since PROLENE mesh is permanently implanted in the body, it is important to understand the initial and longterm biocompatibility of this material, and have assurance that there is no potential for irritancy or carcinogenicity, respectively.

Agarose overlay and elution cytotoxicity tests were conducted at NAmSA with normal production PROLENE mesh (PTS 92-1411) which indicated that the mesh was noncytotoxic in both test systems.

Two-year carcinogenicity studies in rats and dogs were conducted with PROLENE suture as part of the biocompatibility program for the original NDA Submission for PROLENE suture (NDA 16-374). For both species, the tissue reaction was considered minimal, and characteristic of a non-irritating foreign body. The suture was intact, and no evidence of carcinogenicity was observed in either study. Although mutagenicity studies were not conducted, the two longterm studies demonstrating no evidence of carcinogenicity provide strong indirect evidence that PROLENE suture/mesh is not mutagenic as well.

Thomas A. Barbolt, Ph.D., D.A.B.T.
Research Fellow
Corporate Product Characterization

cc: P. Cecchini
H-J. Hoepffner
S. Liu
P. Newlands
M. Rippy
A. Rossetti

*Trademark

7.2 RESIDUES

"The device must be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the products. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure."

The potential contaminants arising out of the manufacture of PROLENE sutures are as follows:

1. Residual Ethylene Oxide (from the sterilisation cycle)

2. Residual Ethylene Glycol and Ethylene Chlorohydrin (from the sterilisation cycle).

1. Residual Ethylene Oxide

Ethylene oxide residues are determined routinely on samples from each sterilisation load. The current requirement is < 100 ppm.

These values are well below those considered acceptable by the current standard ISO 10993-7 - Ethylene Oxide Sterilisation Residues.

2. Residual Ethylene Chlorohydrin and Ethylene Glycol

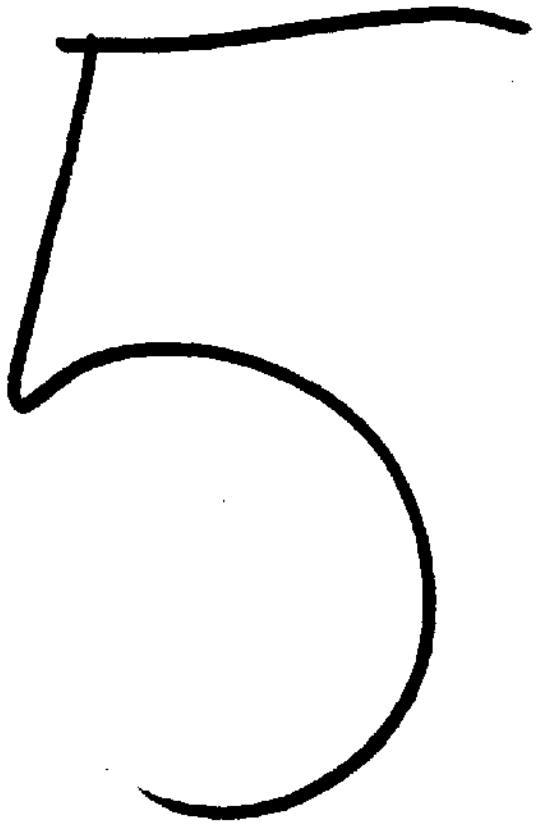
Residual ethylene chlorohydrin and ethylene glycol determinations were carried out on a number of batches of sterilised PROLENE sutures. No residues were found and the detection limit for the methods was as follows:

Ethylene Chlorohydrin - 2.5 ppm, Ethylene Glycol - 5.0 ppm

Due to this testing, routine determinations for these residues was not considered necessary. As in the case with residual ethylene oxide these values are well below those considered acceptable by the current standard ISO 10993-7 - Ethylene Oxide Sterilisation Residues.

7.3 "The devices must be designed and manufactured in such a way that they can be used completely safely with the materials, substances and gases with which they enter into contact during normal use or routine treatment."

The biocompatibility and physical testing carried out on PROLENE ensures that it can be used safely during normal use.



RISK ANALYSIS - PROLENE® MESH STERILE POLYPROPYLENE NON ABSORBABLE MESH

PERFORMED ACCORDING TO BS EN 1441 - MEDICAL DEVICES - RISK ANALYSIS

REF. EN 1441	CHARACTERISTICS (QUALITATIVE & QUANTITIVE) 4.2	POSSIBLE HAZARD 4.3	RISK FOR EACH HAZARD 4.4	FREQUENCY 4.4	RISK ACCEPT-ABILITY 4.5	RISK REDUCTION 4.6	OTHER HAZARD INTRODUCTION 4.7	SAFETY ACCEPTANCE 4.8
4.2 - a	Users: - surgeon - nurses - theatre sisters	- poor delivery	Critical risk	Low	No	Training of personnel User instructions	No	Yes
	Environment: - operating theatre	- gloves cut by packaging	Critical risk	Low	No	Training of personnel	No	Yes
4.2 - b	Implantation site: - implantable device Duration: - long term Invasive contact: - yes Frequency: - linked to number and type of surgical intervention	Biological incompatibility	Allergy, rejection	Very Low	Yes	Biocompatibility tests review	No	Yes
		Non sterile Aseptic hazard	Critical risk	Very Low	No	Ensure sterility of 10^{-6} achieved	No	Yes
4.2 - c	Mesh: Polypropylene thread	Biological incompatibility	Rejection	Very Low	Yes	Biocompatibility tests review	No	Yes
		Cutting error, fault in appearance, mesh damaged, bursting strength too low	Incorrect performance	Low	No	Manufacturing control and Quality Assurance.	No	Yes
		Presence of foreign matter	Product unusable	Low	No			
4.2 - d	Not applicable.							
4.2 - e	Not applicable.							
4.2 - f	Not applicable.							

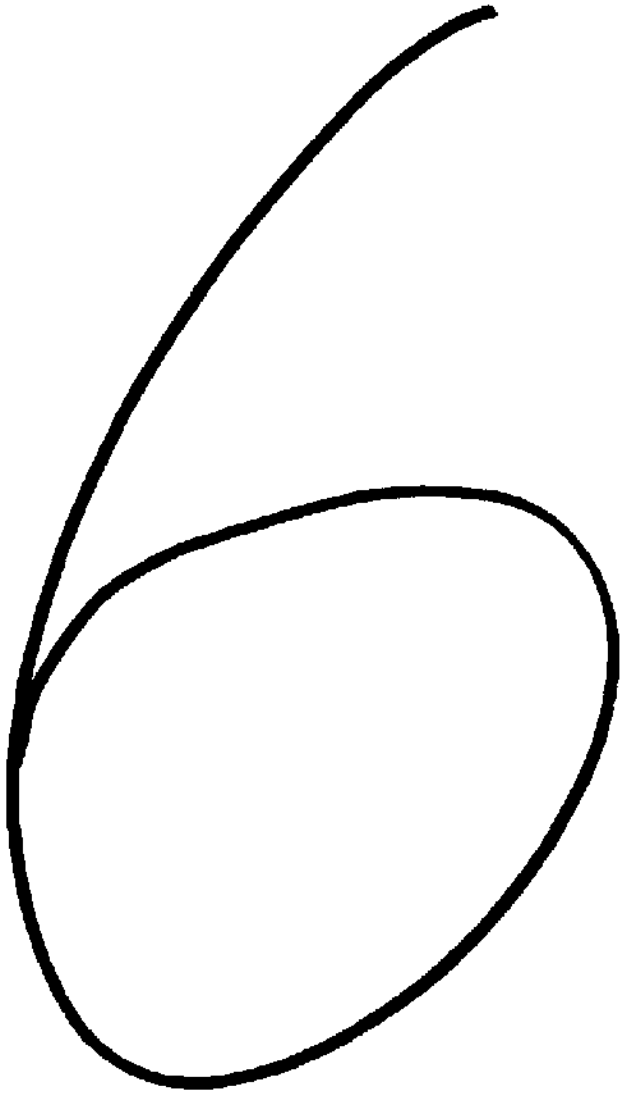
RISK ANALYSIS - PROLENE* MESH STERILE POLYPROPYLENE NON ABSORBABLE MESH

PERFORMED ACCORDING TO BS EN 1441 - MEDICAL DEVICES - RISK ANALYSIS

REF. EN 1441	CHARACTERISTICS (QUALITATIVE & QUANTITIVE) 4.2	POSSIBLE HAZARD 4.3	RISK FOR EACH HAZARD 4.4	FREQUENCY 4.4	RISK ACCEPT-ABILITY 4.5	RISK REDUCTION 4.6	OTHER HAZARD INTRODUCTION 4.7	SAFETY ACCEPTANCE 4.8
4.2 - g	Sterile Device Single Use	Non sterile - aseptic hazard	Critical risk	Low	No	Validation per EN 550 (sterility level: 10^{-6}) Instructions for use	No	Yes
	Packaging:	Sealing incomplete, pouch perforated, presence of foreign substances. Sealing width insufficient, product encapsulation.	Sterility not maintained: - Critical risk - Medium risk	Low Low	NO	Manufacturing control and quality assurance	NO	YES
	Storage stability - 5½ years	Performance/product degradation	- Critical risk	Very Low	No	Verification of stability including sterility up to five and a half years	No	Yes
4.2 - h	Not Applicable							
4.2 - i	Not Applicable							
4.2 - j	Not Applicable							
4.2 - k	Not Applicable							
4.2 - l	Not Applicable							

RISK ANALYSIS - PROLENE® MESH STERILE POLYPROPYLENE NON ABSORBABLE MESH
PERFORMED ACCORDING TO BS EN 1441 - MEDICAL DEVICES - RISK ANALYSIS

REF. EN 1441	CHARACTERISTICS (QUALITATIVE & QUANTITIVE) 4.2	POSSIBLE HAZARD 4.3	RISK FOR EACH HAZARD 4.4	FREQUENCY 4.4	RISK ACCEPT-ABILITY 4.5	RISK REDUCTION 4.6	OTHER HAZARD INTRODUCTION 4.7	SAFETY ACCEPTANCE 4.8
4.2 - m	Environmental influence: - Storage - Transport - User storage	Loss of package integrity Loss of sterility Loss of performance of device	Aseptic hazard Incorrect performance	Low	NO	- Stability testing - Packaging validation - Storage recommendations given in Instructions for Use.	NO	YES
4.2 - n	Not Applicable							
4.2 - o	Not Applicable							
4.2 - p	Not applicable							
4.2 - q	Expiry date: - 5½ years - expiry date stated on the labelling	Information unavailable, incorrect or illegible	Performance of the product	Low	No	Manufacturing control and quality assurance.	No	Yes
4.2 - r	Not applicable.							



PROLENE MESH - CLINICAL STUDIES

1997 PUBLICATIONS:

HERNIOGRAPHY AND ULTRASONOGRAPHY: A PROSPECTIVE STUDY COMPARING THE EFFECTIVENESS OF LAPAROSCOPIC HERNIA REPAIR WITH EXTRAPERITONEAL BALLOON DISSECTION. Dilek, O. N., Bozkurt, M., Arslan, H., Kisli, E., Poyraz, N., and Berberoglu, M. (Department of General Surgery, School of Medicine, Yuzuncu Yil University, Van, Turkey)
Surg. Endosc., 11 (1), 29-31(1997).
(970207)

ORIGIN AND PATHOPHYSIOLOGY OF ABDOMINAL WALL DEFECTS. Klinge, U., Prescher, A., Klosterhalfen, B., and Schumpelick, V. (Chirurgische Universitaetsklinik der RWTH Aachen, D-52057 Aachen, Germany)
Chirurg, 68 (4), 293-303(1997).
THIS ARTICLE IS WRITTEN IN GERMAN
(970405)

TRANSPERITONEAL OR TOTALLY EXTRAPERITONEAL APPROACH IN LAPAROSCOPIC HERNIA REPAIR: RESULTS OF 491 CONSECUTIVE HERNIORRHAPHIES. Kald, A., Anderberg, B., Smedh, K., and Karlsson, M. (Department of Surgery, University of Linkoeping, S-58185 Linkoeping, Sweden)
Surg. Laparosc. Endosc., 7 (2), 86-89(1997).
(970406)

ENDING THE TITANIUM AGE OF SURGERY - LAPAROSCOPIC HERNIA REPAIR WITH THE NEW TENSIOKNOT-SUTURING INSTRUMENT. Abstracts, Annual Congress of the European Association of Endoscopic Surgery, 1st Joint Euro-Asian Congress for Endoscopic Surgery, Istanbul 1997. Schaller, G., Weber, B., Paolucci, V., Gutt, C., and Manegold, B. C. (Department of Surgical Endoscopy, Mannheim, University of Heidelberg)
Surg. Endosc., 11 (5), 575(1997).
(970524)

LAPAROSCOPIC INGUINAL HERNIA REPAIR: AN INDIVIDUALIZED APPROACH? Kraehenbuehl, L. and Frei, E. (Surgical Department, Zieglerspital, CH-3001 Bern, Switzerland)
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